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EXAMINER

KRUSE, DAVID H

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 06/08/2004

18

Please find below and/or attached an Office communication concerning this application or proceeding.

File Copy

Office Action Summary

Application No.

09/754,853

Applicant(s)

HAUGE ET AL.

Examiner

David H Kruse

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 December 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 78-90 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 78-90 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>15 January 2002</u> . | 6) <input type="checkbox"/> Other: _____ |

STATUS OF THE APPLICATION

1. This Office action is in response to the reply filed on 30 December 2003, Applicant's Petition to revive the application having been granted on 6 February 2004 by the Office of Petitions.
2. Claims 1-77 have been cancelled and new claims 78-90 have been entered.
3. The objection to the specification is withdrawn in view of Applicant's amendment.
4. The outstanding objections to the claims are now moot, as such claims have been cancelled.
5. Applicant's statements concerning the restriction requirement is noted by the Examiner and has been addressed in the previous Office action (pages 6-7 of the Remarks).
6. Those rejections not specifically addressed in this Office action are now moot in view of Applicant's cancellation of previously presented claims and entry of new claims.
7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Information Disclosure Statement

8. The supplemental information disclosure statement (IDS) filed on 15 January 2002 has been considered by the examiner. The reference is duplicative of a previous IDS filed, and has been crossed out, but has been considered. A signed copy is attached hereto.

Claim Rejections - 35 USC § 112

9. Claims 78-90 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

At claim 78 (A), it is unclear if the soybean plant bearing an rhg1 SCN resistant allele is homozygous at the locus and if the soybean plant bearing an rhg1 SCN sensitive allele is homozygous for Rhg1, or if the soybean plant bearing the sensitive allele can be heterozygous and also resistant and essentially the same soybean plant bearing the resistant allele, only heterozygous. Hence, the metes and bounds of the claim are unclear.

At claim 78, lines 5-6, the phrase "allele is derived from" renders the claim indefinite because it is unclear what the metes and bounds of "derived" are. There is no indication in the instant claim that the soybean bearing an rhg1 SCN resistance allele is descended from the listed soybean lines, or how the derived allele is introduced into the soybean plant used in the method. Claims 79-85 are also indefinite because they do not obviate this issue of indefiniteness.

Claim 78 is indefinite because the sole designation of a plant by its breeding line name or number, or by a commercial variety designation such as 'A2869' and 'A2069' Asgrow Seeds (see page 48, 1st paragraph of the specification), is arbitrary and creates ambiguity in the claims. For example, the plants disclosed in this application could be designated by some other arbitrary means, or the assignment of the breeding line name could be arbitrarily changed to designate another plant. If either event occurs, one's

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ability to determine the metes and bounds of the claim would be impaired. See *In re Hammack*, 427 F.2d 1378, 1382; 166 USPQ 204, 208 (CCPA 1970). This rejection is repeated for the reason of record as set forth in the last Office action mailed 11 December 2002. Applicant's response filed 30 December 2003 does not specifically address this rejection as it was applied to claim 74, now cancelled, directed to the same issue.

At claim 80, line 2, "capable of detecting" is indefinite because it does not state a definite feature of the claimed method, hence the metes and bounds of the "markers" are unclear. See also claim 81, line 2; claim 82, line 2; claim 84, line 2; claim 86, line 4 and claim 89, line 4.

At claims 81, 83, 85, 87 and 89, the use of arbitrary numbers to designate polymorphisms renders the claims indefinite, hence the metes and bounds of the claims are unclear.

At claim 86, line 2, the limitation "using" renders the claim indefinite because it is unclear what the metes and bounds of "using" are as it relates to "marker assisted selection" as "using" is not a definite method step, hence the metes and bounds of the claim are unclear. See also claim 89, line 2.

At claim 86, line 6, the limitation "introgressing" renders the claim indefinite because it is unclear what the metes and bounds of this limitation are, especially since one or more soybean lines are selected at line 3 of said claim. See also claim 89, line 8.

Those claims not specifically addressed are indefinite because they do not obviate the indefiniteness of the claim(s) upon which they depend.

10. Claims 78-85 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, at line 7, "PI404198B" and "PI43849B" have not been described in the instant Application and did not appear in the claims as originally filed; this is a New Matter rejection.

11. Claims 78-90 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is repeated for the reason of record as set forth in the last Office action mailed 11 December 2002. This rejection has been modified in view of Applicant's cancellation of previous claims and entry of new claims. Applicant's arguments filed 30 December 2003 have been fully considered but they are not persuasive.

Applicant claims methods of introgressing an allele conferring soybean cyst nematode resistance into a non-resistant soybean plant by crossing with a soybean plant bearing an rhg1 CSN resistant allele and screening a segregating population with one or more nucleic acid markers to identify an rhg1 SCN resistant allele. Applicant

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claims a method wherein said one or more nucleic acid markers are capable of detecting one or more polymorphisms.

Applicant describes polymorphisms in various SCN resistant and susceptible soybean varieties in Table 2 on pages 44-45 of the specification.

Applicant does not describe the genus of nucleic acid markers required to identify an rhg1 SCN resistant allele, or the specific polymorphisms as broadly claimed.

Hence, it is unclear that Applicant was in possession of the invention as broadly claimed.

A method is not described if products used in the method are not described. See 64 Fed. Reg. 71427, 71428 (1999), comment No. 4. See also, MPEP § 2163 which states that the claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence. In the instant case the genus of nucleic acid markers are only described by function.

Applicant argues that an adequate written description of a genus of nucleic acids may be achieved by means of a recitation of a representative number of members or of a recitation of structural features common to the members of the genus. Applicant

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argues that the specification provides the complete nucleotide sequence of SEQ ID NO: 2 and as such the specification describes nucleic acid markers that may be used to screen for the presence of an rhg1 SCN resistant allele (pages 8 and 9 of the Remarks). This argument is not found to be persuasive because SEQ ID NO: 2 describes a nucleic acid of 335,913 base pairs and does not specifically describe nucleic acid markers that can be used to identify an rhg1 SCN resistant allele. As shown in Table 2 on pages 44-45 of the specification, the nucleotide bases described do not specifically identify an rhg1 SCN resistant allele because specific single nucleotide polymorphisms appear in both resistant and susceptible soybean varieties.

12. Claims 78-90 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection is repeated for the reason of record as set forth in the last Office action mailed 11 December 2002. This rejection has been reiterated as it is directed to methods of using nucleic acid markers to identify an rhg1 SCN resistant allele. The Examiner notes that the breadth of the claimed methods is broader than that encompassed by the previous claims. Applicant's arguments filed 30 December 2003 have been fully considered but they are not persuasive.

Applicants argue that they need only establish a single mode of making and using the invention (page 10, 3rd paragraph of the Remarks). Applicants argue that the specification provides methods for, and a working example of, screening plants to

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identify those plants that carry an rhg1 SCN resistant allele by means of various markers, and that the specification describes the nucleotide position of single nucleotide polymorphisms and insertion/deletion polymorphisms (INDELS) in various soybean lines (page 10, 4th paragraph of the Remarks). Applicants argue that case law does not require each and every compound within a claim to be equally useful for each and every contemplated application (page 11, 3rd paragraph of the Remarks). These arguments are not found to be persuasive in the instant case. In the instant case, Applicants' single mode argument is not persuasive because the instant claims are directed to a method, not a product, and as such it is pursuant upon Applicants to teach how to use the claimed methods within the full breadth of the claims. Given the teachings of the instant specification, it is unclear as to what degree Applicant has enabled the claimed methods. Table 2 on pages 44-45 of the specification teaches various single nucleotide polymorphisms of various soybean lines, but there does not seem to be a correlation between such polymorphisms and the presence of an rhg1 SCN resistant allele. See *In re Fisher*, 166 USPQ 18, 24 (CCPA 1970) which teaches "That paragraph (35 USC 112, first) requires that the scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art. In cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific laws. In cases involving unpredictable factors, such as most chemical reactions and physiological activity, the scope of enablement

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obviously varies inversely with the degree of unpredictability of the factors involved.”.

As directed to Applicants’ arguments as to the teachings of the specification, at page 54, Applicant only gives general guidance on how to use molecular markers of various types to identify traits in plants, at page 64 gives general guidance on data analysis and does not teach specifically how to use the claimed invention. As the nucleic acid markers are crucial to practicing the claimed methods, it is Applicants’ burden to teach one of skill in the art at the time of the invention how to use the invention without undue trial and error experimentation, that being screening through a myriad of nucleic acid markers to identify those that can be used to identify an rhg1 SCN resistant allele as broadly claimed.

13. Claims 78-85 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection has been reiterated as it is directed to methods of using nucleic acid markers to identify an rhg1 SCN resistant allele. Applicant’s arguments filed 30 December 2003 have been fully considered but they are not persuasive. This rejection is directed to the issue that the invention appears to employ novel plants to practice the claimed method.

Applicant argues that the soybean lines required to practice the claimed invention are publicly available as evidenced by the Germplasm Resources Information Network (GRIN) Database at the National Plant Germplasm System of the Agricultural Research

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Service (USDA) (page 12, last paragraph of the Remarks). This argument is not found to be persuasive because it is Applicants' burden to enable the claimed invention, not a third party. To illustrate this point, the Examiner notes that soybean line PI 540556 is protected under PVP 9000171, and that GRIN has a disclaimer that rights to use must be acquired from the donor/developer, said donor/developer having no legal obligation to enable Applicant's invention by allowing the use of soybean line PI 540556. See *Ex parte Humphreys* 24 USPQ2d 1255, 1259 (BdPatApp&Int, 1992) which teaches that the ability of others to obtain material from a third party prior to and after the filing date of an application does not establish that upon issuance of a patent on such application that such material will continue to be accessible to the public. This issue also arises with soybean lines 'A2869' and 'A2069' which Applicant teaches as being the property of Asgrow Seeds, Des Moines, Iowa (page 48 of the specification), who has no legal obligation to maintain said soybean lines and make them publicly available in order to enable Applicants' invention.

Claim Rejections - 35 USC § 102

14. Claims 78 and 79 are rejected under 35 U.S.C. § 102(e) as being anticipated by Lightfoot *et al* (US Patent 6,300,541 B1, filed 14 January 1997).

Lightfoot discloses a method of conveying soybean sudden death resistance into non-resistant soybean germplasm comprising using marker SATT309 to identify a resistant soybean and introgressing said resistance into a non-resistant soybean germplasm (claim 4). Lightfoot discloses that said source of resistance can be from a descendant of Jack (the commercial name for soybean line PI540556) (claim 6).

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Lightfoot also discloses that marker SATT309 segregates with rhg1 SCN resistance (Figure 23). Because one of skill in the art would be using a descendant of Jack and selecting using marker SATT309 prior to ingressing into a non-resistant soybean, one of skill in the art would in fact be practicing the method in the order recited by Applicant, and selecting members of a segregating population having an rhg1 SCN resistant allele. Soybean line Jack has yellow soybeans. See *Integra LifeSciences I Ltd. V. Merck KGaA* 50 USPQ2d 1846, 1850 (DC SCalif 1999), which teaches that where the prior art teaches all of the required steps to practice the claimed method and no additional manipulation is required to produce the claimed result, then the prior art anticipates the claimed method.

Conclusion

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR § 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR § 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


16. Claims 80-90 are free of the prior art which neither teaches nor fairly suggest the claimed method identifying single nucleotide polymorphisms or INDEL mutations.

17. No claims are allowed.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (571) 272-0799. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Amy Nelson can be reached at (571) 272-0804. The fax telephone number for this Group is (703) 872-9306 Before Final or (703) 872-9307 After Final.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (571) 272-0547.



David H. Kruse
10/16/38

David H. Kruse, Ph.D.
4 June 2004